

**Analysis of Expansion of Access to Care
Through Use of
Telemedicine and Mobile Health Services**

**REPORT 3: TELEMEDICINE POLICY: QUALITY ASSURANCE,
UTILIZATION REVIEW, AND COVERAGE**

by

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EXECUTIVE SUMMARY

This report has four major objectives: 1) discussion of information obtained during the course of interviews with medical directors for Medicare fiscal intermediaries, private insurance companies, and health maintenance organizations concerning Medicare policy options; 2) discussion of policy options regarding quality assurance and quality improvement for telemedicine; 3) discussion of policy options regarding utilization review of telemedicine services; and 4) discussion of coverage policy.

The interviews were open-ended and semi-structured, and were conducted over the telephone. The topics covered included knowledge of telemedicine and of specific telemedicine programs, understanding of the decision regarding reimbursement in Georgia, approaches to quality assurance, utilization review, and reimbursement methodology.

As was the case in Report 2 under this contract, no blanket endorsement of telemedicine's effectiveness can be made at this point. There are many areas in which telemedicine appears to be safe, effective, and acceptable to patients. There is also little question that in remote rural areas, telemedicine has the capacity to increase access to medical care.

We address a number of approaches to coverage, and encourage careful formulation of policy accompanied by research to deal with unanswered questions, and to evaluate the effects of policies once they are instituted. The options range from a very conservative tack involving further study of the effectiveness of telemedicine, through one that would approve a number of applications for reimbursement. In some cases, reimbursement might be approved contingent upon a requirement that providers collect data that can be used to assess effectiveness of telemedicine.

Thus, we recommend an approach to coverage policy based on the taxonomy of telemedicine applications presented in Report 2. That taxonomic scheme was based on: 1) what is known about the effectiveness of various telemedicine applications, and what research remains to be done; and 2) various processes of health care delivery that cut across lines of specialization. The taxonomy contains four categories of telemedicine application. The first category includes telemedicine applications that are widely thought to be effective, and require research on patterns of reimbursement and costs to the system. These could probably be reimbursed, but research should be conducted to help refine coverage policy, and to assess utilization and effects on the health care system. The second category includes applications that are assumed to be effective, but whose possible effect on the system is unknown. For many of these, reimbursement may be appropriate, but research needs to be conducted dealing with health services issues such as practice patterns, role of nonphysician providers, costs, and related matters. The third category includes those areas of telemedicine which have not yet been demonstrated to be effective, or on which more basic research remains to be done in order to establish minimal standards. Here, careful consideration must be given to approval of coverage, and applications may need to be approved on a case-by-case basis. A good deal of research remains to be done on some of these applications. The fourth category includes applications which are currently experimental, or which anticipate future integration of various advanced technologies. As a rule, these are not ready for coverage.

Utilization review and quality assurance can be used in tandem to insure the delivery of quality health care while minimizing abuses of the system. Properly conducted, utilization review should demonstrate cases of under-utilization as well as over-utilization, either of which may have adverse effects on health status. We encourage careful study of the effects and the effectiveness of telemedicine, both prior and subsequent to decisions about coverage policy. A rational approach to decision-making that is informed by well-designed and carefully conducted research is important.

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CHAPTER 1

INTRODUCTION

A. PROJECT AND REPORT OVERVIEW

1. Project Overview

The initial purpose of this project was to examine available information on the expansion of access to care through the use of telemedicine and mobile health services. As the project developed, it was decided that telemedicine should be the exclusive focus. The primary project objective is to examine issues related to the development of a Medicare coverage policy for such services. The major consideration is whether services provided using telemedicine technologies are medically safe and effective.

The approach to the project involves literature review, development of a conceptual framework for the analysis of studies examining effectiveness, selected case studies, review of coverage policies of private third-party payers, and examination of utilization review and quality assurance/improvement models currently in operation as part of existing telemedicine systems.

Three interim reports and a final report are planned. Report 1 (Grigsby, Kaehny, Schlenker, et al., 1993) covered the literature review and analytic framework. Report 2 (Grigsby, Sandberg, Kaehny, et al., 1994) contained case study data and presented a taxonomic system for classifying telemedicine applications with respect to their need for further evaluation. Report 3 (this report) covers utilization review, quality assurance/improvement, and coverage policies related to telemedicine. The final report will consolidate Reports 1-3. Preparation of the final report will follow a meeting of a technical advisory panel comprised of experts in telemedicine, health care policy, and health services research. Revisions may also be made in the first three reports as a function of newly discovered literature, experience gained on site visits, and the input of study consultants. The final report will present overall conclusions and recommendations.

2. Outline of the Current Report

This is the third report of the project. It summarizes the information obtained from telephone interviews with medical directors of health maintenance organizations, several large health insurance companies, and third party payers for Medicare. The purpose of these interviews was to obtain an overview of policies considered or formulated by any of these entities for coverage, quality assurance, and utilization review of telemedicine services. Chapter 1 provides background and introductory information. Chapter 2 presents information obtained during the course of these interviews. Chapter 3 consists of a discussion of quality assurance. Chapter 4 addresses utilization review, and Chapter 5 contains a discussion of coverage policies and options, including alternative payment methods.

Our findings suggest that little work has been done with regard to setting policy or establishing models in telemedicine. Presently, only in Georgia has approval been given by the local third-party payer medical director for reimbursement of telemedicine services. Medicaid has approved coverage in Georgia as well as in Kansas and Montana. Blue Cross/Blue Shield of Kansas is the only other payer that had approved coverage at the time of this report. As a consequence, there is little precedent to draw on in the process of developing policy.

CHAPTER 2

TELEPHONE INTERVIEWS

A. APPROACH TO THE INTERVIEWS

The RFP for this project anticipated that the published literature might contain information regarding models for utilization review and quality assurance, and information regarding coverage policy. The information obtained from the literature review for this project was then to be integrated with the findings of interviews with medical directors from different payers.

Because there are few guidelines for this area, and because different payers might have very different interests and positions *vis à vis* telemedicine, the original proposal did not call for a formal survey. Instead, we used a semi-structured interview format comprised of a number of open-ended questions with directions for followup. Because the primary purpose of these interviews was to obtain information concerning policies and models that may have been developed, and because it was expected that a majority of the medical directors would have limited knowledge of telemedicine, we have not conducted any qualitative data analysis. Instead, we intended to use the information obtained from medical directors to facilitate the development of models and policy options.

The interviews dealt with the following issues:

- o Knowledge of telemedicine and telemedicine programs.
- o Knowledge of existing reimbursement methods.
- o The status of any negotiations with telemedicine providers.
- o Attitudes toward reimbursement for telemedicine.
- o Ideas about how coverage should be handled (e.g., coding, payment schedules).
- o Attitudes toward various limitations on coverage policy (e.g., specific applications, restrictions on geographic regions or provider types, patient conditions).
- o Ideas about coverage policy for teleradiology.
- o Models for quality assurance/quality improvement (QA/QI).
- o Models for utilization review.
- o Recommended areas for future research.

We interviewed the medical directors of twenty-seven Medicare Part B carriers, four private insurance companies, and two health maintenance organizations (HMOs). Four Medicare medical directors refused to participate, and five medical directors never returned telephone calls.

B. DATA OBTAINED FROM INTERVIEWS

1. Knowledge of Telemedicine

Most respondents described themselves as being relatively unfamiliar with telemedicine, although all of them had heard something about it. Most were aware that a reimbursement policy had been established in Georgia with the Medical College of Georgia, but few knew the details. Of those with whom we spoke, only two of the Medicare medical directors had dealt with the issue at a local level. Neither medical director for either HMO was aware of any plans within their organization to develop telemedicine programs, and neither had given the issue much thought. None of the medical directors with private insurance companies had attempted to develop policies for telemedicine.

2. Should Telemedicine be Reimbursed?

Close to two-thirds of those individuals interviewed thought that telemedicine services should be reimbursed. Of the remainder, half were opposed, and the other half did not know or had no opinion. Even those who supported reimbursement were somewhat cautious. They usually noted that their support of reimbursement was contingent upon the development of proper guidelines, and under certain circumstances. Several supporters thought it should not be used routinely, but should be reserved for urgent situations. A need for further research was emphasized by several of the medical directors. They recommended further study of telemedicine's effectiveness and of issues related to utilization and reimbursement.

The potential value of telemedicine for diagnostic consultation was generally acknowledged, although there were some concerns about the lack of a hands-on examination in telemedicine. There appeared to be some agreement that any service would be appropriate as long as the patient benefits and the process of the consult is proper.

There was greater enthusiasm for teleradiology and telepathology than for clinical medicine involving videoconferencing. The reasoning was that these activities involve no patient contact and require only the transmission and interpretation of images, and are therefore more reliably conducted by telecommunications media. There was support for the use of telemedicine by most specialties with the exception of psychiatry, where opinion was more evenly divided. Some felt psychiatry was inappropriate when done by telemedicine. There was also opposition to the provision of medical services to nursing homes via telemedicine.

Support for reimbursement of teleradiology was about equivalent to support for general telemedicine. Most felt the technology was adequate, but it did not appear that most were familiar with the literature on the efficacy of teleradiology. Some questioned the need for the specialty, arguing that in most cases radiology consults were not so critical that they could not be sent by overnight mail if necessary.

3. Should Teleradiology Have a Separate Procedure Code?

Teleradiology is currently being reimbursed under Medicare, although it has not been approved explicitly. Because teleradiology has no separate procedure code, it is impossible to estimate the volume of these services, or to track utilization of teleradiology. The general opinion of those surveyed was that teleradiology should be coded in such a way that it could be tracked in claims data. Approximately 35% of the sample favored the development of a new CPT code, while a larger percentage thought only a modifier should be used. One respondent suggested that there be two modifiers, with one used by the sending (remote) facility and the other used by the receiving (consultant) facility. The ability to discriminate teleradiology from conventional radiology was thought to be beneficial in tracking utilization, avoiding double billing, and conducting research on outcomes.

4. How Should Reimbursement be Handled?

Few of the medical directors surveyed had given this issue any previous thought, so that responses were tentative and fragmentary, and there was little agreement among them. Among the suggestions provided were the need to establish relative values for telemedicine services, and the need to set fairly clear parameters for utilization and review. There was concern about the possible need to pay two providers and two technical fees (one to each facility), although some respondents thought this was appropriate. Opinion was divided regarding whether telemedicine services should be considered

identical to conventional medical care from the standpoint of reimbursement, and this determined whether interviewees thought new procedure codes should be devised.

5. Should Restrictions be Placed on Coverage?

The vast majority of medical directors held the opinion that coverage restrictions were critically important, although some warned against excessive restrictions that limited access to care. The most common sentiment was that an unrestricted reimbursement policy would be inflationary and would lead to significant overutilization. It frequently was suggested that demonstration studies be conducted prior to establishing a final policy. The urgency of the medical situation was often cited as a determining factor, with urgent and emergency situations being more clearly viewed as eligible for reimbursement, or cases in which a patient was too unstable to transfer.

There was general agreement that rural areas would be likely to benefit from telemedicine, but there was more controversy over whether intra- and inter-city networks should be approved. Some challenged the need for telemedicine in densely populated areas with access to good medical care. *Medical necessity* was proposed as a requirement for reimbursement. In the case of telemedicine, medical necessity could entail either: 1) an acute situation in which patient transport is contraindicated or where delay is potentially harmful to the patient; or 2) a situation in which patients in remote settings cannot get directly to a physician. One proposal was to restrict the kinds of medical applications that could be provided, but no specific suggestions were provided.

6. Should Services Involving Nonphysician Providers be Reimbursed?

The utilization of nonphysician providers is a controversial subject. Most respondents agreed that nurse practitioners and physician assistants should be reimbursed, but their answers were often qualified. Many believed that these services should be covered only when no physician is available and this is the best possible option. The example was given of a difficult delivery being handled by a nurse practitioner when no obstetrician is available locally. As a general rule, issues of access and medical necessity dominated thinking on this matter. A few respondents expressed the concern that reimbursement of services involving a nurse practitioner or physician assistant was liable to encourage overutilization.

In a situation when the physician assistant or nurse practitioner who legally requires supervision calls in the supervising physician on a case, reimbursement was not thought to be warranted. On the other hand, if the consulting physician is an actual consultant and not a supervisor, the consultant should be reimbursed appropriately. The nonphysician provider should charge the ordinary fee for an office visit, and nothing for the telemedicine consult. When the practitioner puts in a considerable amount of time on a telemedicine service, it was suggested that a supplementary office visit fee could be charged. One respondent suggested that the telemedicine consultant and primary care provider should each be paid a portion of the ordinary consulting fee, the total amount not to exceed the usual fee for a direct service. Only one medical director thought that nurse practitioners and physician assistants should not be involved in telemedicine at all.

7. Should Telemedicine Services Have a Separate Procedure Code?

Most respondents agreed that telemedicine consults should be uniquely identifiable; opinion was split over whether a unique code or a modifier should be used. A modifier would identify a service as having been provided by telemedicine, permitting tracking of these services, and would be enough to ensure no double billing. Those who favored a unique code suggested that this would reduce the

chances for confusion in coding and billing. New relative values could be computed for new procedure codes.

8. In Physician-to-Physician Services, Should Both be Paid?

Opinion was somewhat divided on this issue, but most respondents answered in the affirmative. However, these responses often were qualified somewhat. For example, one respondent recommended that HCFA consider what the providers are actually doing during the consult. When a primary care provider did little during the consult, he or she would bill only for an office visit, and would receive no further payment. One medical director suggested that the primary care provider could charge a fee that included no work component, but only the practice expense and malpractice components.

Because both providers are involved in medical care during a medically necessary telemedicine consult, several medical directors recommended that they both be reimbursed. It was noted that the referring physician is not typically reimbursed at present, and that to reimburse those physicians would increase expenditures and utilization. There was no clear idea how to balance fairness to providers with the need to keep utilization and expenses in check.

9. If Both Physicians are Paid, How Much Should Each Get?

a. Consultant: Most medical directors suggested that the consultant be paid the usual consulting fee, based on the nature and scope of the consultation. It was suggested that a written consult report should be kept in the chart of the referring facility, and that the consultant should not receive extra payment for this. Another recommendation was that the consultant be paid less than usual since in most cases the consultant would not be using his or her own equipment, and thus would have no practice expense to reimburse. The money thus saved might be used to defray the cost to the remote facility for transmitting the images, data, or other information. Other suggestions were that new relative value units be computed, and that consultants be paid in accordance with their skill and the time involved.

b. Primary Care Physician: The general opinion was that the primary care physician should be paid the standard office visit fee, with the usual practice expense component. Some felt that an office visit extension code could be used if the time spent on a patient visit was excessive because of the telemedicine contact itself. When the referring physician is required to play a significant role in the consult (e.g., acting as the "surrogate hands" of the consultant during an exam), then the primary care provider would be allowed to bill for that service.

10. How Might Abuse or Overutilization Become a Problem?

Every respondent recognized the potential for abuse in telemedicine, although the concerns expressed are not necessarily unique to telemedicine. Furthermore, none of the respondents alleged that these situations had actually occurred, but instead they noted that these were areas in which they thought it was necessary to be alert to possible abuses.

Losing sight of the medical necessity of services was a major concern, as medical directors feared telemedicine might be used simply to confirm one's impressions. The prospect of overutilization was raised repeatedly, not only for monetary incentives, but also simply because it would be available. One possible abuse raised was that of billing for the highest paying code from a range of codes when the actual services provided should be billed at a lesser fee. Some of the more egregious instances of potential abuse cited involved such things as double billing (by practitioners at both ends when this

is not authorized), kickbacks, referral to specialists in one's own "dummy corporation," teleconsultation within a single facility (between 2nd and 3rd floor of the same building, for example), aggressive marketing of specialized services, and simple overuse to generate revenue.

In order to diminish the potential for abuse, respondents made several suggestions. One was that reimbursement for telemedicine should be tightly restricted. Limiting or eliminating compensation for telemedicine was suggested as an extreme form of control. Finally, careful documentation, tracking, and utilization review were seen as important regulators of usage.

It should be noted that, given the current very low volume of telemedicine services (Allen, 1993), overutilization is certainly not an issue at the present time.

11. How Could Utilization Review be Handled?

The most common response was that telemedicine needed a unique identifier (modifier or code) to permit tracking of utilization. Post-payment audits and chart reviews were recommended in order to guarantee that the services were medically necessary. It was suggested that there be practice guidelines or parameters to permit a standardized means of determining the appropriateness of the services. An emphasis was placed on quality assurance activities in conjunction with utilization review.

Some respondents recommended thorough research on the subject, and one suggested the establishment of a number of telemedicine pilot projects, each with a different objective (e.g., emergency care, chronic disease management). The results of these studies could be used to set guidelines for assessing whether the services are provided appropriately.

CHAPTER 3

QUALITY ASSURANCE/QUALITY IMPROVEMENT IN TELEMEDICINE

A. INTRODUCTION TO QUALITY ASSURANCE/QUALITY IMPROVEMENT

1. Definitions of Health and Quality

The process of ensuring that Americans have access to health care that is of uniformly high quality is complex. One must first establish a conceptual definition of quality care, and then operationalize that definition. The next focus is on the unit of analysis. Are we concerned about physicians, providers more generally, or the institution in which they work? In some instances, the health care system itself could be responsible for deficiencies in health care. To what extent do technological issues affect the quality of the care that is provided? How do we know whether apparent problems in health care delivery are actually related to certain patient variables? That is, to what extent does a heavy case mix (e.g., poorly compliant patients, sicker patients, differences in comorbidity) affect perceptions of quality care? How is quality measured, and who does it?

Controversies surrounding health care reform, the move toward managed care, and increasing health care costs have focused attention on quality assurance. If major changes come about in the way medical care is provided, the many participants in different aspects of the health care system have a considerable interest in maintaining quality care. It is against this background that telemedicine is being introduced.

According to the World Health Organization (WHO), health should be considered to be "complete physical, mental, and social health and not merely the absence of disease or infirmity" (WHO, 1948). A state of health is present when an individual is experiencing optimal functioning along these three dimensions. This is close to the conceptual definition offered by Brook and McGlynn (1991), who argue that "a minimum acceptable definition of health should include maximizing biological and clinical indicators of organ functions as well as physical, mental, and role functioning in everyday life."

Taking this broad definition of health as a starting point, the assessment of health encompasses more than the evaluation of certain clinical or physiologic markers. Hence measures of cognition, functional status, and general health perceptions have been developed and studied extensively in relation to a wide range of health outcomes (Bergner et al., 1981; Feinstein et al., 1986; Guyatt et al., 1993; Hirsch et al., 1990; Kaye et al., 1990; Patrick & Bergner, 1990; Patrick & Deyo, 1989; Reuben et al., 1992; Reuben & Siu, 1990; Sager et al., 1992; Siu et al., 1990; Strawbridge et al., 1992; Ward et al., 1990; Winograd et al., 1991).

Good quality health care can be broadly defined as care that has a positive effect on these various aspects of health, whereas poor quality care has a negative effect on health (Brook & McGlynn, 1991). Because undesirable health outcomes are inevitable, and since patient preferences may not reflect what providers think is best for them, quality of care can also be defined probabilistically as "the degree to which health services to individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (Institute of Medicine, 1991).

The political philosophy of Quality Assurance (QA) has undergone a shift in recent years. In the past, it has frequently been the case that QA was seen as a means of discovering instances of

substandard care and of correcting the offenders. Many institutional risk management programs, for example, have used this approach to anticipate possible malpractice litigation, and in its most extreme form, sanctions may be applied to individuals who have provided the substandard care. The publication of hospital mortality data, and an emphasis on regulatory agencies with disciplinary power are approaches to QA that are consistent with this approach.

More recently, many writers have promoted the concept of Quality Improvement (QI), or Continuous Quality Improvement (e.g., Berwick, 1989; Cooney, 1991; Institute of Medicine, 1991; Kritchevsky & Simmons, 1991). The basic orientation in QI is to assume that most providers are doing their best, that they are motivated to improve their performance, and that the emphasis should be placed on continuously attempting to improve everyday health care. Ferreting out bad health care providers, identifying "outliers," is not the primary goal. It is assumed that there will always be "Bad Apples" (Berwick, 1989), and while it is necessary to identify them, those who argue in support of this position assert that it is also important to continuously nudge the quality of care in a more positive direction. This is the general tack recommended by the Institute of Medicine in its study of QA for the Medicare program.

2. Assuring the Quality of Health Care

QA and QI activities may be broken down into assessment of quality and assurance of quality. The former is intended to identify factors that may need to be changed to improve health care, while the latter involves instituting changes and monitoring them. In general terms, QA may be thought of as studying the *structures, processes, and outcomes* involved in health care delivery (Donabedian 1980, 1988).

The structures in telemedicine programs are the organizational, professional, and technological resources available. This category includes videoconferencing equipment, medical peripherals (e.g., electronic stethoscope, otoscope), and the telecommunications medium. It also encompasses personnel, including physician and nonphysician providers who may utilize the system. Finally, when we discuss structures we refer to the health care organization itself, and to the network that is created by the use of a telemedicine system.

The processes are those activities that characterize the system. That is, what is done to the patient, and what is done for the patient (even when he or she is not present)? Thus, processes may include the manner in which the patient is introduced to the use of telemedicine, the demeanor and interpersonal effectiveness of the consulting specialist in interacting with the patient, the way in which a remote examination is conducted, the configuration of the exam room, and a myriad of related parameters. These processes may be evaluated at the level of the individual practitioner, the telemedicine "team," if there is one, and the system or network.

Processes may be analyzed along a number of dimensions. Care is *appropriate*, for example, if it improves patient health outcomes and if "patients prefer this treatment and these outcome probabilities among those offered by the alternatives" (Wennberg, 1991). There may be considerable *geographic variation* in the utilization of various medical services, reflecting a number of factors. For example, depending on where one lives in New England, Wennberg and his associates (Wennberg & Gittelsohn, 1973; Wennberg, Gittelsohn & Shapiro, 1975) found that the likelihood of a woman having a hysterectomy by the age of 70 varied from 20% to 75%.

One means of assessing whether the processes are appropriate is through the use of *clinical practice guidelines*. The primary purpose of these guidelines is to standardize the treatment of various

conditions (Audet, Greenfield & Field, 1990; Brook, 1989; Woolf, 1990, 1992, 1993). Practice guidelines have been developed for a range of diseases and disorders, and are somewhat controversial. Ignoring for the moment the concerns expressed by many physicians about the potential problems with the use of practice guidelines, they may nevertheless be used as a frame of reference for comparison of the processes in which health care providers engage.

The *assessment of outcomes* has been promoted extensively over the past ten or fifteen years. Outcome research attempts to relate changes in patient health to specific medical care interventions. The outcomes assessed may be long-term (e.g., mortality and morbidity), short-term, or intermediate (e.g., patient satisfaction with a consult, patient compliance). Such research may evaluate the effectiveness of treatment of a specific condition or disease, changes in general health status, changes in perceptions of one's health, functional status, accuracy of diagnoses, complication rates (e.g., infection, iatrogenic disorders), physiologic variables, or any of a number of other outcomes. Unfortunately, well-designed outcomes research is expensive and time-consuming, and difficult to design and conduct. Good outcome studies are not available for many treatments and diseases, and as a result the data needed to assess outcomes in QA activities are lacking.

The choice of either outcomes or processes as the focus of examination may in part be determined by the nature of the assessment one wishes to conduct. Outcomes may be best analyzed in relatively large or population-based studies, while process variables may be more effectively studied when one is interested in looking at a small sample, or at single instances of care such as individual telemedicine consults (Luft, 1991). In either case, it is important to develop telemedicine-specific measures of outcome and process.

B. QUALITY ASSURANCE AND TELEMEDICINE

1. Level of Analysis of Telemedicine QA Activities

Quality assurance activities that focus on telemedicine services are rather different from QA applied to a specific surgical procedure (e.g., cholecystectomy) or medical intervention. Telemedicine is not a treatment *per se*, but is a medium through which medical care can be provided. Furthermore, at least at present, the number and kinds of treatments that can be provided via telemedicine are quite limited. Telemedicine is valuable primarily for diagnosis, consultation, and triage or emergency evaluation. It may be used for followup medical care, especially for routine postoperative appointments or medication checks.

It thus makes little sense, in quality assurance, to compare the effectiveness of telemedicine with the effectiveness of conventional medical care for the treatment of specific diseases or conditions. Telemedicine may provide a mechanism by which a patient can consult with a cardiologist who receives a transmission of the patient's echocardiogram, but cardiac catheterization (and a host of other procedures) cannot be done by telemedicine. It therefore is important to approach QA activities for telemedicine from a different angle.

In the second report under this contract (Grigsby, Sandberg, Kaehny, et al., 1994), we presented a taxonomic scheme for categorizing different telemedicine applications. The taxonomy we described was based on various *processes* of care rather than on specific diseases, organ systems, or specialties, and on the status of specific applications in relation to current research needs.

This taxonomy consists of four categories of current telemedicine applications. The first group consists of applications that are plainly effective. They can be readily defined, and their

implementation would be relatively straightforward. The second group consists of applications that are likely to be effective, but the implications of implementing programs in these areas are unclear. They would require a certain amount of health services research before we could thoroughly understand their effects on the health care delivery system. The third group consists of applications for which the safety and effectiveness are currently unknown, or for which basic research is required to specify requisite technical parameters. The fourth group consists of applications which at this point are entirely experimental, or which anticipate the integration of different existing advanced technologies. We have included robotics under both the third and fourth categories, since some limited clinical experimental use is already being made of surgical robots. The integration of robotics and virtual reality is somewhat more distant.

2. Illustration of Use of the Telemedicine Taxonomy

To demonstrate how quality assurance might be conducted with telemedicine, we might examine outcomes in the first category of applications, those widely thought to be effective. Among these are several applications that have been used successfully in one or more existing telemedicine programs, including initial urgent evaluation of patients, triage decisions, and pretransfer arrangements. Such activities might include emergency neurosurgical, cardiac, or trauma consultation. They would be one-time consults involving a specialist, the patient, and a primary care provider at a remote site. Medical and surgical followup and medication checks also fall in this category. These might include postsurgical follow-up care between the specialist and patient, either with or without the primary care provider present, depending on the purpose of the consult. Finally, supervision and consultation for primary care encounters in remote sites where a physician is not available could probably be done reliably via telemedicine. These would be one-time consults with a primary care physician on one end and a nurse practitioner or physician assistant with the patient at a remote site.

One could, for example, study short-term and intermediate outcomes of the use of telemedicine for surgical followup. An investigator might examine patient and provider satisfaction with this mode of service delivery, compliance with the surgeon's instructions or recommendations, or infection rates. Comparisons could be made with patients receiving conventional postoperative followup, using either case control or prospective quasi-experimental research designs. This approach would obviate the need for outcome studies of a wide range of medical disorders since the focus of attention is the effectiveness of telemedicine for surgical followup. Although a study of this kind might be somewhat ambitious as a QA project within a single institution, carefully conducted outcome studies that control for factors like case mix and geographic variation in utilization could provide data for comparison.

Similarly, when telemedicine is used for triage decisions and pretransfer arrangements, it would be a relatively straightforward matter to assess, retrospectively, the appropriateness of the decisions made using telemedicine. A case control design might permit the analysis of the rate of appropriate transfer of patients from rural community hospitals to larger medical centers, evaluating both overuse and underuse of the more intensive setting. Even in the absence of a case control design, triage decisions could be subjected to a *post hoc* independent assessment, and the results used to influence future behavior.

3. Use of the Analytic Framework for the Effectiveness of Telemedicine

An important aspect of quality assurance in telemedicine would be the continuous monitoring of diagnostic accuracy. In this case, instead of the analysis of processes (e.g., followup, triage) described above, one would analyze the accuracy of diagnoses made using telemedicine. One might study all

diagnoses made within a specialty (e.g., dermatology), certain aspects of diagnoses within or across specialties (e.g., normal vs. abnormal), or specific conditions (e.g., heart murmur).

In the first report under this contract (Grigsby, Kaehny, Schlenker, et al., 1993), we presented an analytic framework that would facilitate assessment of the effectiveness of telemedicine. In the second dimension of that framework, we were concerned with evaluating that aspect of medical effectiveness that involves the accuracy of diagnoses made via telemedicine. This was because so much of telemedicine as it is currently practiced is a diagnostic process.

Given the potentially enormous scope of medical problems that might be encountered by a telemedicine consult service, we sought to simplify the process of studying effectiveness by focusing on a more limited range of conditions. We therefore proposed that, rather than attempting to study the efficacy of telemedicine across all diseases, certain conditions be selected that could be considered indicators of effectiveness. These would be used to demonstrate the safety of telemedicine services. Within each specialty there are illnesses whose initial manifestations may be subtle, or that represent particularly difficult diagnostic issues. Other conditions are relatively easy to diagnose. In chest radiography, for example, pneumothorax may be difficult to detect. The criteria for selection of these conditions were described in detail in Report 1. In routine QA activities, one might also wish to examine the accuracy of diagnosis for conditions that are easier to detect.

If the performance of diagnosticians using telemedicine procedures is satisfactory for an effectiveness indicator condition, then it may be assumed that the procedure is accurate for less difficult diagnostic questions. We did not recommend setting *a priori* levels of accuracy that must be met. Instead, the degree of accuracy required of a diagnostic procedure for a given condition must be in part a function of such factors as appropriateness of the procedure and effect on access to care. The sensitivity and specificity of diagnoses could be computed, and the expected numbers of false positive and false negative cases computed. Depending on such factors as the nature, severity, and course of the illness in question, policy decisions could be made regarding the quality of care provided using telemedicine for such a diagnostic procedure.

4. Quality Assurance and the Structure and Processes of Care

In the examples discussed above we emphasized quality assurance in relation to various outcomes of health care. Also important are quality monitoring activities that study the structural and process variables, especially insofar as they are associated with favorable or unfavorable outcomes.

The "art of care" (Brook & McGlynn, 1991), reflected in the interpersonal skills of the provider, is an important aspect of process. Physicians who are unable to allay their patients' anxiety, or who have difficulty relating to their patients as human beings, may experience higher rates of noncompliance as well as other adverse outcomes. This issue may be particularly germane to telemedicine, in which the ordinary face-to-face interaction and physical contact are absent. Because it is a common practice among telemedicine programs to videotape all or a portion of the telemedicine consults that occur, the interpersonal process is one of many process variables that can be studied in great detail. Not only can these videotapes provide data regarding individual providers, but they may also illuminate quality problems in other aspects of the way telemedicine is implemented.

Numerous structural variables are amenable to analysis from a QA perspective. If diagnostic accuracy is to be maintained, especially in specialties like dermatology, technical parameters such as the level of illumination and calibration of color need to be monitored. If adequate bandwidth were

available, it might be interesting to determine whether patient satisfaction differs with compressed versus uncompressed video. Using videotapes of telemedicine encounters, one might, for example, be interested in comparing rural primary care physicians with nonphysician providers in presenting patients for specialist consultants. Another possibility would be to study differences in the ways that consultants from different specialties deal with similar problems using telemedicine. Cherkin, Deyo, Wheeler & Ciol (1994), for example, found significant differences in the approach taken to the diagnosis of low back pain by physicians practicing in eight different specialties. Although the study did not involve telemedicine, the findings suggest a number of interesting possibilities for examining issues of quality of care in telemedicine as well.

5. Summary: Quality Assurance and Telemedicine

The assessment of quality, and the implementation of changes to improve quality in telemedicine, can be approached as described above. As is often the case in medical care, quality assurance activities will proceed contemporaneously with demonstrations of the effectiveness (or its lack) of telemedicine.

In our first report (Grigsby, Kaehny, Schlenker, et al., 1993), we noted that few data exist in the research literature to support the effectiveness of non-radiologic uses of telemedicine. A few studies have been conducted, most with very small samples. In part this reflects the fact that telemedicine is presently a low-volume enterprise, so that large-scale research has been impossible. In addition, with a few exceptions, those individuals who have been instrumental in developing telemedicine programs have been clinicians or administrators, and not scientists. Their focus has not been on evaluating the effectiveness of telemedicine, but on providing services to groups that previously had limited access to those services.

Little research has been conducted to assess the effectiveness of telemedicine. Nevertheless, if one takes into consideration the information obtained through case studies of telemedicine programs in the course of this project, it seems clear that the technology has significant potential. Considerable research is necessary, however, to demonstrate the effectiveness of telemedicine across a wide range of applications.

CHAPTER 4

UTILIZATION REVIEW AND TELEMEDICINE

A. OVERVIEW OF UTILIZATION REVIEW

The services provided in the health care system may vary in quality as a function of the competency of a given provider and the resources available to him or her. They may also be inappropriately utilized—overused, underused, or used in the wrong circumstances. As noted in the preceding chapter, there is a great deal of geographic variation in the frequency with which certain services are performed, suggesting there may be little agreement regarding what should be considered appropriate levels of utilization. Furthermore, this variation makes it difficult to assess the meaning of variations in utilization in the context of small studies or single facilities. Prior to the movement of the system toward DRGs and prospective payment, there was little incentive for providers to control the utilization of various services when they were reimbursed on a fee-for-service basis. This has obvious implications for the control of inflation and expenditures in the health care sector, but overutilization may have adverse consequences for quality of care as well.

A very high rate of utilization of a given service throughout the system may expose patients to increased levels of risk associated with unnecessary procedures (e.g., risk of complications, adverse effects, iatrogenic and nosocomial disorders, anxiety, discomfort), without any increased benefit (Palmer, 1991). It may also be that more facilities or providers will offer the service, but many of these may do such a low volume of procedures that the quality of care is inadequate. A growing body of research, for example, has shown that there is a relationship between the quality of certain services provided by hospitals or caregivers, and the frequency with which that service is provided (e.g., Flood, Scott, and Ewy, 1984a, 1984b; Keeler, Rubenstein, Kahn, et al., 1992; Luft et al., 1979, 1987, 1990).

Underutilization may be problematic in that necessary or beneficial care may be unavailable to patients. Payment mechanisms that limit access to appropriate services lead to underutilization and poor quality (Schroeder, 1991). Thus, in health care systems with capitated reimbursement, underuse may reflect a cost-cutting device that adversely affects patient outcomes or the process of care. While overuse may be relatively easy to document, underuse is more difficult to assess, especially outside the context of managed care. Other factors limiting access could of course be the number of qualified providers available and patient noncompliance. Finally, utilization may simply be inappropriate because the wrong service is provided.

Utilization review (UR) can be an important aspect of QA insofar as it is used to assess less than optimal patterns of use of services, and in many institutions it is difficult to distinguish quality assurance from utilization review. We often know little about optimal use, and it is often variable given the individual patient's circumstances and physical condition. A major purpose of UR, however, may also be to control costs by reducing the availability of services, and in some cases the desire to reduce expenses may be in direct conflict with the provision of good quality care. Nearly twenty years ago, Altman and Eichenholz (1976) observed that advances in technology, expansion of services, and addition of specialized services are all factors likely to increase health care expenditures. There is now concern in some quarters that telemedicine, which involves all three of these factors, could lead to significant increases in spending on medical care.

Utilization may be controlled by a variety of mechanisms. In some cases, bottlenecks may be introduced into the system, making services absolutely or relatively unavailable. Lengthy waiting lists may contribute to attrition among many patients on the list, and patient queuing may make it

impossible for patients to have access to a provider as quickly as they may need or want. Payers may regulate service use through deductibles, copayments, and limits on covered benefits. These approaches limit the availability of certain kinds of care irrespective of their appropriateness for any given patient. If a major incentive for the use of telemedicine is to increase access to health care, the use of these methods is likely to be counterproductive.

Utilization review may also be conducted on a case-by-case basis. Preauthorization of services such as elective surgery, pre-admission certification, or the requirement of a second surgical opinion, may have some impact on utilization. The value of these approaches is not entirely clear (Lindsey & Newhouse, 1990). In some settings, UR is conducted concurrently with a patient's treatment, and there are facilities in which a utilization review nurse or provider team are very involved in treatment planning meetings. Finally, retrospective review is quite common. This may be done by the institution, by peer review organizations (PROs), or through review of claims by payers. Retrospective review does not affect the ongoing treatment of patients, but feedback from the process may influence future provider behavior, especially when payment is limited or withheld for certain services.

The use of prospective payment for DRGs is one example of an approach to controlling the number and expense of services used with patients.

B. UTILIZATION REVIEW AND TELEMEDICINE

1. General Remarks

Utilization review might be conducted for procedures and applications conducted by telemedicine for several reasons. Telemedicine is a new technology, and we have a great deal to learn about its efficacy and cost effectiveness. Past experience has demonstrated a tendency for new technologies to be overutilized. Further, because telemedicine is a new technology, there remains some uncertainty about the range of appropriate and inappropriate applications. This uncertainty creates a potential for either intentional or unintentional misuse, which could have significant implications for the quality of patient care and for health care expenditures.

It is possible to use utilization review in a punitive manner, as a kind of sanction applied when one is concerned about overuse of services. While it clearly has an appropriate regulatory role, it was the suggestion of the advisory panel that utilization review should be conducted so that it has a facilitating, educational role. When used properly it may improve the delivery of health care.

2. Practice Guidelines

One possible approach to utilization review of telemedicine services is a variation on the theme of practice guidelines for different telemedicine applications (e.g., followup, triage). Such guidelines could facilitate UR activities by providing a standard against which use of telemedicine might be measured. Properly designed, practice guidelines might help to identify underuse of telemedicine, as well as overuse. For example, the charts of a sample of patients who did not get a telemedicine referral could be reviewed with reference to appropriate guidelines. This use of practice guidelines for utilization review could be undertaken by practitioners, institutions, or payers.

The kind of guidelines that might be developed, like the taxonomic scheme described previously, would not be primarily disease- or specialty-specific. Instead, the focus for guidelines should be on more general processes of care. There would thus be guidelines for the use of telemedicine in emergency trauma situations, medical-surgical followup, or complicated pregnancies. Some

systematized set of procedures would also be warranted for periodic brief follow-up consults with patients having chronic disorders like chronic obstructive pulmonary disease, diabetes, or end-stage renal disease. To the extent possible, telemedicine practice guidelines should make explicit the situations in which the use of telemedicine is indicated, and the frequency and intensity of services appropriate for those situations. It should be understood that these would be general guidelines, suggesting a range of service utilization that would be reasonable. More specific indications for the use of telemedicine in individual cases would be a function of the diagnosis and clinical condition of any given patient, and these would not be covered by telemedicine practice guidelines.

The guidelines that might be employed would not recommend specific approaches to the assessment and treatment of any individual disease or disorder. Instead, they would provide direction in the use of telemedicine across a range of conditions. The process of developing telemedicine guidelines would thus differ from the approach ordinarily taken (Audet, Greenfield & Field, 1990; Brook, 1989; Woolf, 1992) for the treatment of such specific phenomena as pain, pressure sores, or heart disease.

To develop practice guidelines it is first necessary to review the literature critically in order to establish empirically-based procedures. For clinical telemedicine, this literature is essentially nonexistent (Grigsby, Kaehny, Schlenker, et al., 1993). Guidelines of this kind should be founded on outcome studies. Without an understanding of how telemedicine affects various patient outcomes, discriminating appropriate from inappropriate uses of telemedicine, except for the most obvious cases, is not possible. Without an adequate research base, decisions concerning appropriateness are likely to be based on factors such as enthusiasm for telemedicine, or concern about the potential for increased expenditures. Utilization review may thus initially be more descriptive than analytic.

Given adequate research on the effects of telemedicine on costs, outcomes, and access to care, it may be possible to engage in the subsequent steps required for guideline development (Brook, 1989). These include the specification of guidelines, the evaluation of their validity and reliability, and the monitoring of their utility, with refinement or revision as needed. Although this process should be supported by the appropriate government agencies, the actual development of guidelines might best be assigned to independent contractors in consultation or collaboration with professional organizations.

The development and use of practice guidelines, it should be noted, is a new and relatively unexplored aspect of health care delivery. The utility of practice guidelines has not yet been conclusively demonstrated, and whether they would have value for telemedicine is an unanswered empirical question. Nevertheless, we expect that guidelines of the sort we are suggesting, based on applications and general processes of care, might be somewhat easier to develop than disease-specific guidelines.

3. Pre-authorization of Telemedicine Services

In general, the need for prior authorization of telemedicine services appears minimal. For certain applications, such a requirement is inappropriate. Using telemedicine for triage decisions, emergency consultation, and pre-transfer arrangements could not reasonably be subjected to review prior to providing the service. On the other hand, the use of pre-authorization in connection with ongoing services for patients with chronic illnesses may be workable, if one assumes that such situations provide an opportunity for inappropriate use. Whether pre-certification should be adopted for referrals for routine specialty consultation is less clear, although it might be argued legitimately that a routine requirement of approval prior to such consults could discourage necessary and reasonable care, and represents an unjustified interference with the primary care physician's decision making and

management of the patient's treatment. Perhaps a somewhat stronger case for this type of review prior to specialist consultation could be made for those situations in which the primary care provider is not a physician. One should not assume, however, that experienced nurse practitioners and physician assistants practicing under a physician are unqualified to make these judgments themselves.

In the case of surgery, it is a common practice to require a second opinion in order to prevent unnecessary operations from being performed. To obtain a second opinion about using telemedicine seems pointless, although videoconferencing itself may be a viable mechanism for obtaining a second surgical opinion from a specialist in an urban medical center. It should be noted, however, that the long-term value of second surgical opinions has been called into question (Lindsey & Newhouse, 1990).

4. Concurrent and Retrospective Review of Telemedicine Utilization

Concurrent review is used primarily in association with hospitalization. By monitoring the use of services and length of stay, UR puts pressure on physicians to avoid tests and procedures that are not absolutely necessary, and to discharge patients as rapidly as is practical. The primary area of telemedicine in which concurrent management of utilization might be of value would be in the ongoing treatment of patients with chronic conditions. In some cases, regular specialist consultation might be used when a patient could be managed equally well by a primary care provider, with occasional consultation as needed.

Retrospective review of telemedicine services may be the most reasonable and effective way to assess their appropriateness, at least until a sufficient body of data has been obtained to develop norms for prior or concurrent review. This process could take place at several different levels. At the patient level, payers might conduct reviews of claims. At the institutional level, facilities could randomly sample patients and conduct chart reviews to determine whether telemedicine services were necessary and appropriate. An outside audit of Medicare cases is one possibility. Such a review might be similar to those conducted by PROs to determine the necessity and appropriateness of hospital admissions and readmissions. Thorough documentation of consults would be important for this approach to UR to be successful, and this might include review of archived videotapes of telemedicine consultations. Routine review of tapes would be impractical. Some facilities, however, tape all consultations, and when a chart review suggests that more data are necessary, tape review might be helpful.

5. Need for More Research

Regardless of which approach one adopts to utilization review, the dearth of research on the effectiveness of telemedicine makes UR difficult to conduct. We do not yet have adequate data regarding the effects of telemedicine on patients' health status, nor do we know the extent to which videoconferencing will be used as a medium for providing medical care. The ultimate effect of telemedicine on costs and expenditures is equally uncertain, although some proponents of telemedicine contend that this approach to health care delivery is very cost-effective. If they are correct, then the focus of utilization review might be to encourage the use of telemedicine. The problem is that we have little information on many of these issues.

Given the considerable geographic variation in utilization that has been reported previously (e.g., Wennberg & Gittelsohn, 1973; Wennberg, Gittelsohn & Shapiro, 1975), demonstration projects and evaluations of one or two sites are unlikely to provide the data that are needed to conduct a program of utilization review and management. This is especially so given the differences in research design and methodology that might characterize different programs, confounding attempts to make

meaningful comparisons. Our previous work (Grigsby, Sandberg, Kaehny, et al., 1994) demonstrated that there is significant variability among telemedicine programs, and even among remote sites within a single network. Demographic, clinical, and case mix factors may all have a significant effect on the utilization rates within telemedicine systems. Unless research is conducted on a relatively large scale, it will be very difficult to acquire the information necessary to make well-informed decisions. Such research should focus not only on clinical outcomes, but on changes in practice patterns, costs and benefits, access and utilization, and the process of providing care. Well designed cross-cutting studies of this kind could be used to help establish rational practice guidelines.

Finally, it is important to note that the study of medical outcomes, upon which many of these decisions (and guidelines) must be made, is a very immature science. Just as telemedicine is new and its appropriate applications are not fully determined, so is the study of outcomes relatively new and not without its limitations and flaws (Anderson, 1994; Jollis, Ancukiewicz, DeLong, et al., 1993; Wennberg, 1992). Hoped to be a short-cut from the lengthy process of randomized controlled trials, outcomes research has been problematic on several counts.

Practice guidelines are in their infancy and have only been developed for a limited number of conditions. It is difficult to account for the many different ways physicians are trained, and further complicating matters is the great variability among patients diagnosed with the same condition.

In short, there is a need for a significant amount of further research. It is important to know about the efficacy, effectiveness, and cost effectiveness of these new procedures. Because of the considerable expense and time involved in studying long-term outcomes it may be tempting to focus primarily on telemedicine outcomes of a short-term and intermediate nature. In the process of studying telemedicine, it is important to continue to adjust and improve current methods of measuring quality in general. Telemedicine research should be informed by current developments in outcomes research.

CHAPTER 5

COVERAGE POLICY AND TELEMEDICINE

A. GENERAL ISSUES IN COVERAGE POLICY

1. New Technologies and Health Care Expenditures

The introduction of new health care technologies tends to be followed by their rapid proliferation and subsequent increases in spending for medical services. Although the effect of approving reimbursement for telemedicine is uncertain, past experience suggests that it should not be surprising if telemedicine leads to increased spending by Medicare. The End Stage Renal Disease program, for example, led to expenditures exceeding the initial projections. As the purchaser of health care services, Medicare is faced with the challenge of covering safe and effective medical care while avoiding excessive expenditures. This involves the establishment of a reimbursement structure that is fair to providers and patients without being too costly.

2. Conceptual Difficulties with Telemedicine Coverage

Unlike most technological advances in medicine, telemedicine is not used for the diagnosis or treatment of specific conditions. Instead, telemedicine is a medium via which a wide range of services may be provided. In effect, it extends the reach of the provider's office. It offers nothing that cannot be done currently by a physician in his or her office, and in fact it is capable of providing far fewer services.

In principle, if telemedicine is primarily an extension of the provider and not a new diagnostic or therapeutic mechanism, it logically ought to be treated like conventional medical care. There are, however, at least two factors that complicate this. First, from the perspective of resource-based relative value, it is not clear whether the work performed by the telemedicine consultant is identical to the work performed by a conventional consultant. Further, when the primary care physician is involved in a consult, this differs substantially from the current pattern of practice, and the relative value of the work performed by the provider in that case has not been established. Second, because the effectiveness of telemedicine has not been demonstrated for a number of applications, we cannot assume *a priori* that telemedicine and conventional service delivery are identical in this regard.

In some cases, telemedicine provides services that substitute for something provided under conventional medical care. Teleradiology, for example, may merely substitute for another way of doing radiology. On the other hand, many telemedicine consults will involve services that would not have been provided without telemedicine. Rural patients with chronic illnesses, for example, may be followed more closely by subspecialists. This distinction may be important in the process of establishing coverage policy, since the former will ostensibly not increase costs and the latter is likely to do so.

B. COVERAGE POLICY AND TELEMEDICINE

1. Safety and Effectiveness of Telemedicine

In the first report under this contract, we concluded that, while the published research literature supported the use of teleradiology for many applications, there were few data showing the

effectiveness of telemedicine consultation. In the second report, we discussed a series of case studies of telemedicine programs, during which we had the opportunity to observe telemedicine consultation and to discuss telemedicine with users of the system. We found considerable provider support for the technology, but also observed that professional acceptance of telemedicine is not universal. A minority of providers, most of whom had used or were currently using telemedicine, expressed reservations about the effectiveness of the technology. Nevertheless, the majority of providers interviewed expressed the opinion that they could perform their work quite adequately via telemedicine.

Subsequent to our literature review and case studies, we concluded that various telemedicine applications could be categorized with respect to the degree to which they were considered effective. We conceptualized these applications as falling into several classifications reflecting the amount of support that existed for their effectiveness. This taxonomy is discussed in the previous chapters and a brief summary is presented here.

The first category, which encompasses applications widely thought to be effective, includes: 1) the use of telemedicine for triage, emergency consultation, and pre-transfer consultation; 2) the use of telemedicine for routine medical and surgical followup; and 3) the provision of services to remote areas where no physician is available. The second category consists of applications that are probably effective, but which are likely to have an unpredictable effect on the health care system. These include: 1) single session diagnostic evaluations; 2) extended diagnostic workups; 3) short-term management of acute or self-limiting conditions (e.g., complicated pregnancy); and 4) long-term management of chronic illness (e.g., end-stage renal disease). The third category consists of applications requiring basic research. This category includes applications for which technical requirements for visual imaging or sound quality have not yet been established, or the efficacy of which is undemonstrated. The final category includes applications based on new and untested technologies adapted for use with telemedicine. These include telerobotic surgery or interventions, virtual reality interfaces, and the integration of neural networks or expert systems into telemedicine technology.

In making decisions about coverage policy and the effectiveness of telemedicine, we have suggested the use of the taxonomy proposed in Report 2 and the analytic framework proposed in Report 1. The analytic framework recommends an approach to considering diagnostic accuracy of telemedicine applications, and deals with other factors that need to be considered in making coverage decisions. These include the effects of telemedicine on access to care and the appropriateness of the services provided.

Unfortunately, only teleradiology (and to a lesser extent telepathology) has been studied with the degree of rigor necessary in peer-reviewed research on outcomes and diagnostic accuracy. Telemedicine consultation has not been subjected to the close scrutiny that is often applied to new medical technologies. It was therefore necessary for us to reach some of our conclusions based primarily on what we observed, and on an informal assessment of provider acceptance of the technology.

As noted in the report to Congress of the Physician Payment Review Commission (PPRC, 1994), "the limiting factor for good coverage decisions today is the lack of high-quality information on which to base them. Because health plans generally do not gather primary data to use in technology assessments, the assessments they perform depend heavily on the evidence available. They typically find that few, if any, relevant rigorous studies have been done" (p. 223). It is thus not surprising that this should be the situation *vis à vis* telemedicine, especially given that most existing telemedicine

programs have been in operation for less than three or four years, and given the sudden development of powerful market forces pushing for expansion and approval of telemedicine.

2. Should Telemedicine Services be Covered and Reimbursed Under Medicare?

Too many aspects of telemedicine remain primarily investigational, and too little is known about the possible effects of telemedicine on the health care system, to permit a blanket endorsement of the technology. Nonetheless, certain telemedicine applications appear to be effective and warrant coverage. We therefore propose that coverage decisions be based on the taxonomy we proposed in Report 2 under this contract.

The proposed taxonomy was intentionally somewhat imprecise with regard to what applications were to be included or excluded for coverage purposes. This was because too little is known about the effectiveness of telemedicine, both generally and in relation to specific uses. Some more definitive criteria for classification, perhaps devised by an expert clinical panel, may be useful. Such criteria should initially be considered subject to change as we learn more about the utility of telemedicine.

a. Applications Widely Accepted as Effective: It seems reasonable that telemedicine applications in this category should be covered. They appear to be effective and for the most part provide improved access to care, especially for persons in frontier, remote, or poor rural areas. While one might argue that no services should be covered until their medical effectiveness has been demonstrated by means of randomized controlled trials, we reject this position as too extreme. Nevertheless, even if services in this category are approved for coverage it will be important to conduct research on their utilization and quality, and on their effects on various aspects of the health care system.

b. Applications that are Probably Effective, but with Unknown Effects on the System: Telemedicine applications in this category are probably effective, but research on this issue needs to be done. Here, the options range from denial of coverage until adequate research has been completed through full approval. Although a reasonable argument could be made for either of these positions, it appears that some form of coverage may be warranted. The need for research on these applications, however, is greater than for those in the first category. One course of action would be to approve some applications for coverage without restrictions (e.g., management of complicated pregnancies or chronic illnesses), while applying restrictions to other applications until their effectiveness has been demonstrated. For example, dermatologic diagnostic workups might be covered in the context of the study of their effectiveness. This would be consistent with the recommendation of the PPRC (1994, p. 220) that "when evidence of the safety and efficacy of an experimental technology or treatment is not yet sufficient to warrant coverage, plans generally should still contribute the cost of standard therapy toward the evaluation of the technology or treatment in approved research studies." Programs providing these services could be required to collect data on outcomes, effectiveness, and complications.

c. Applications that Require Basic Research: Decisions concerning applications in this category would probably need careful consideration, perhaps on a case-by-case basis. We do not recommend full coverage for these services. In many cases (e.g., robotic surgery), the application is clearly experimental, not obviously safe or effective, and should not be covered. Considerable research remains to be done on these applications before they could be approved. In general, it seems reasonable to expect that the developers of these technologies should bear the costs (private funding, grants, public offerings) of demonstrating safety, efficacy, and effectiveness without expectation of reimbursement from Medicare.

d. Applications Using New and Untested Technologies Adapted for Telemedicine: Applications in this category (e.g., the use of telerobotic laparoscopic technology or virtual reality interfaces for surgery) should be considered experimental or investigational, and should not be covered until their value has been demonstrated by sufficient methodologically sound research.

e. Teleradiology: Teleradiology is already covered by Medicare and other providers, although because these services cannot be identified from claims data it is impossible to estimate the volume of such services. As we concluded in Reports 1 and 2 under this contract, certain aspects of teleradiology seem clearly effective. The transmission of data that are acquired digitally (e.g., MRI, CT) seems not to be a problem. Perhaps the greatest difficulties are with radiographs, especially chest films and x-rays of subtle orthopedic fractures (Scott et al., 1993).

One potential approach to dealing with radiology would be to establish a separate identifier for teleradiology that would permit tracking of the use of this application from claims data. For consultative purposes, reimbursement of most teleradiologic services seems reasonable. For diagnostic CT and MRI, the same is probably true. For diagnostic chest and bone films, however, because the literature does not support the accuracy of telemedicine relative to conventional radiography, services might be reimbursed in the context of studies of outcomes, in which the original films are later read and diagnoses compared with those based on digitized images. When the diagnostic accuracy of teleradiology for these applications is demonstrated, the requirement for research could be dropped.

3. Restrictions on Coverage

We have already discussed placing restrictions on coverage in the context of demonstrating the effectiveness of certain applications. Other kinds of restrictions might be used in order to control costs and utilization. One reason for doing this might be to allow time to assess the effects of telemedicine coverage on health care expenditures as reimbursement is phased in. It might also be the case that a policy decision is made to permit coverage only for specific groups or regions.

A limitation of coverage to programs in rural areas would be likely to constrain Medicare's expenditures for telemedicine. Assuming that telemedicine increases access to care for persons not currently receiving care, it is reasonable to expect that, at least over the short term, telemedicine might increase Medicare expenditures. Limiting coverage to rural areas would allow HCFA to study the financial implications of coverage before expanding reimbursement to urban telemedicine services. Although existing telemedicine programs provide services chiefly to residents of rural areas, many programs are now being developed and it is only a matter of time before videoconferencing is used for health care delivery in urban areas. Within metropolitan areas, it might be possible to restrict coverage to persons in underserved groups or areas.

Besides restricting coverage by geographic region, limits could be placed on the specific applications reimbursed. A useful research strategy in this regard is to conduct studies comparing telemedicine costs and outcomes in rural and urban networks, especially in comparison with conventional modes of health care delivery. Providers might be reimbursed who agreed to collect the data necessary to conduct such studies. Another way to restrict coverage would be to limit reimbursement to providers who met specific qualifications.

4. Approaches to Payment

Although many approaches to payment are possible, those briefly discussed here include fee-for-service payment to physicians, possible facility fees for telemedicine services, DRG inclusion for inpatient hospital telemedicine services, bundling, and capitation. Overall, we recommend that

variations in existing payment approaches be empirically evaluated and that demonstrations test new payment approaches as telemedicine services and technologies are evolving.

a. Fee for Service Payment to Physicians: Fee for service payment provides few incentives to control utilization, and when applied to new technologies it may lead to overutilization and increased health care expenditures. Nevertheless, for both inpatient and outpatient consultation, much of telemedicine is likely to be reimbursed on this basis. Several aspects of this approach therefore should be considered.

First, diversity of opinion exists regarding whether telemedicine should be treated the same as conventional health care delivery. From the perspective of the consultant, the work involved is quite similar, although the consultant is unable to perform a hands-on examination of the patient. When a primary care physician is involved in the consult at the remote site, however, this marks a departure from the ordinary practice of medicine. In conventional practice, the primary care provider is not involved, so there is only one fee charged—that of the specialist. In telemedicine, primary care physicians (and nonphysician providers) are likely to expect reimbursement for their time. This may be a reasonable expectation given the opportunity costs of telemedicine for these physicians, and the fact that they may be involved in the examination of the patient to some extent.

It might be feasible to use existing procedure codes for the consultant, albeit with a modifier to indicate the use of telemedicine. Thus one might use the standard codes for consultation, varying by the complexity of the consult. The use of modifiers might be limited, however, by the fact that apparently not all current data processing systems accept modifiers. Thus, additional codes for consultations may be necessary. If the work seems to differ significantly from conventional care, it may be appropriate to calculate new relative values for the consultant. For the primary care physician, it also appears advisable to develop new codes, and to develop relative values for these services. Such changes could probably be made using the current Medicare update and refinement process, without the need for new time studies. The physician practice expense component of the fee schedule might be adjusted to reflect the costs of purchasing and using the telemedicine equipment (including line charges, which vary markedly in different regions of the country and even within single states).

The arrangement negotiated by the local Medicare carrier and the Medical College of Georgia currently involves five initial service codes and four followup codes for physician services under telemedicine. While this may be a workable approach, some consideration should be given to the possibility that fewer codes (perhaps three for both initial and followup services) would allow more accurate classification, prevent "code creep," and still permit fair reimbursement.

b. Limiting the Number of Providers and their Charges: Assignment of benefits and participating provider arrangements have been used already in Medicare, and could be utilized to control telemedicine fees as well. Competitive contract bidding is another possible option to reduce costs, especially as the number of telemedicine programs increases significantly. It may be that some programs become major regional or national players in the medical care market, and competitive bidding, such as has been done with California Medicaid (Medi-Cal) contracting hospitals, may help to reduce costs.

c. Geographic Differentials in Reimbursement: Although telemedicine is being hailed as a provider of care to rural areas, experience over time may demonstrate that many of these areas simply have too small a population base to permit rural providers and facilities to maintain infrequently used telemedicine equipment. Some consideration should thus be given to possible differential

reimbursement rates as a function of geographic location. This could take the form of larger payments for remote areas that have few providers.

d. Facility Fees for Telemedicine Services: Many providers of telemedicine services are currently lobbying for facility fees for use of telemedicine equipment. Under one scenario, a telemedicine consult would yield a fee for the consultant and the primary care physician, and facility fees for both the rural and hub sites. When one considers that using conventional health care delivery results in only the consultant fee being paid, it is clear that Medicare expenditures could increase significantly.

If access is a primary policy objective, facility fees might be linked to volume of services, with centers providing fewer telemedicine services receiving a higher fee (although this could encourage the spread of low-volume telemedicine programs, with possible outcome quality effects). Facility fees might also be paid only to rural hospitals or clinics. Because small rural hospitals have less opportunity to use their equipment (and thus pay for it) than might hospitals in areas with a larger population, the equipment is essentially more costly for them to purchase and maintain. If desired, this could be dealt with by means of adjusting facility fees for geographic, demographic, and case-mix factors.

An alternative approach to this issue would be to provide no service-based facility fee, but to adjust the capital component of Medicare hospital reimbursement to reflect the availability and utilization of telemedicine. One proposal of the technical advisory panel for this study was that an annual payment to each facility be negotiated for capital costs and operating expenses. This payment might be independent of volume, in order to avoid some of the concerns discussed above. It was argued that a negotiated payment would be superior to a retrospectively determined cost reimbursement since the latter might encourage facilities to purchase unnecessarily expensive equipment, and not to make efforts to cut costs in a reasonable manner. Such an approach was suggested as an initial approach that would be applicable to start-up situations and would be feasible as long as the number of telemedicine sites was relatively small. The approach would be replaced once adequate data were available on costs related to volume and other factors.

e. Inclusion of Inpatient Telemedicine Services in DRG Payments: In some cases, a patient in a rural community hospital may be provided a consult with an urban specialist via telemedicine. Under prospective payment, telemedicine services might be treated no differently than conventional medical care. When payment is handled through DRGs, payments for telemedicine could be included in the amount paid for any given DRG. The standard DRG payments are already adjusted according to geographic region and urbanization, and some adjustment of the non-labor component of these rates might be made for rural hospitals that are part of a telemedicine network.

f. Bundling: One approach to cost containment is to bundle various telemedicine components into a single payment. Physician fees, line charges, and a facility fee might all be included in a single payment, for example, for both outpatient and inpatient telemedicine services. Experimentation with various bundling arrangements could be conducted under demonstration projects.

g. Capitation: Telemedicine services can be included as part of a benefit package covered under a capitation payment rate. In such circumstances, the organization receiving the capitation payments has financial incentive to avoid overutilization of all services, including telemedicine. However, the value of services provided by telemedicine should be reflected by appropriate levels of capitation payments. The quality of care may be improved by telemedicine through, for example, the provision of regular followup contact between specialists and patients with chronic disorders. To illustrate, assuming that a capitated payment was made for the psychiatric treatment of chronic schizophrenics,

or for care of patients with severe diabetes or end stage renal disease, provision in the capitation rate should be made for regular telemedicine consults with the appropriate specialist or subspecialist.

5. Summary: Coverage Policy for Telemedicine

Although the research literature on the effectiveness of clinical telemedicine is practically nonexistent, other data suggest that to proceed with reimbursement of some telemedicine services would be reasonable. Earlier in this report we suggested possible telemedicine applications that might be covered by Medicare, and we addressed a number of options for payment methodology. The issue is complex, and will require extensive research after policy decisions are made in order to refine the process. Regardless of the direction taken by HCFA, it would be advisable to conduct a large-scale, cross-cutting evaluation, beginning with baseline data to be obtained before coverage changes are made and designed to assess utilization, costs, outcomes, and any unanticipated consequences of the policy decision during the first several years after a policy is established.

APPENDIX A

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